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10/563,110	06/19/2006	Hanne Muller	Q-92287	1130

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SUGHRUE MION, PLLC		
2100 PENNSYLVANIA AVENUE, N.W.		
SUITE 800		
WASHINGTON, DC 20037		

EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1614	

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10/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/563,110

Applicant(s)

MULLER ET AL.

Examiner

Timothy E. Betton

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-43 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20, 22, 23, 25, 26, 28, 29, 31, 32, 34, 35 and 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 21, 24, 27, 30, 33 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 January 2006, 1 sheet</u>                                   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1614

### **DETAILED ACTION**

Applicants' election without traverse in the reply filed on 27 August 2007 is acknowledged.

#### ***Restriction/ Election***

Accordingly, Applicants hereby elect the invention of Group I, i.e., Claims 18, 21, 24, 27, 30 and 33 without traverse. Claims 36-38 are amended to be directly or indirectly dependent on Claim 18.

#### ***Status of the Claims***

Claims 18-43 are pending. Claims 19, 20, 22, 23, 25, 26, 28, 29, 31, 32, 34, 35 and 39-43 are withdrawn from consideration. Claims 36-38 are amended to read on the elected subject matter. Claims 18, 21, 24, 27, 30, 33, and 36-38 read on the subject matter elected and are pending for examination.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Joint Inventors*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 21, 24, 27, 30, 33, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa et al (USPN 4906479) and Makula, R.A. (Phospholipid Composition of Methane-utilizing bacteria, J Bacteriol. 1978 June; 134(3): 771-777, printed pages 1 and 2, (Abstract only), which are both in view of Rawlings et al. (USPN 4217370), Barrows (USPN 5851574), and Fang et al. (Characterization of methanotrophic bacteria on the basis of intact phospholipid profiles, FEMS Microbiology Letters 189 (1), 67-72, printed pages 1 and 2, (Abstract only).

Kitagawa et al. teach cultivating Artemia as a feedstuff for larvae of cultivated fishes or crustaceans is provided, which feedstuff for cultivation is a product obtained by treatment of breaking the cell wall of monocellular algae, the thus obtained Artemia having a high survival rate, the body length thereof being large and the content of eicosapentaenoic acid and docosahexaenoic acid in the total fatty acids therein being much higher than those of conventional feedstuffs (Abstract only).

As disclosed above, Kitagawa et al. discloses a feedstuff for juvenile fish.

Kitagawa et al. discloses a microbial lipid formulation via the cultivation of *Artemia* by which eicosapentaenoic acid and docosahexaenoic acid are in high dietary content.

Makula teaches phospholipids of *Methylococcus capsulatus*, *Methylosinus trichosporium*, La Paz, and OBT were examined in relation to their qualitative and quantitative composition. *M. Capsulatus* exhibited a phospholipid composition consisting of phosphatidylethanolamine, phosphatidylglycerol, cardiolipin, and phosphatidyl-choline. The esterified fatty acids were predominantly C16:0 and C16: 1. *M. trichosporium*, La Paz, and OBT exhibited an essentially identical phospholipid composition consisting of phosphatidylmonomethylethanolamine, phosphatidyl-dimethylethanolamine, phosphatidylcholine, and phosphatidylglycerol. Only trace amounts (less than 1%) of cardiolipin were found in these organisms. The major esterified fatty acid in these organisms was C18: 1 (87 to 90%). The monounsaturated fatty acids from all four organisms consisted of both cis and trans isomers, each of which contained delta8, delta9, delta10, and delta11 double-bond positional isomers (Abstract only).

As disclosed above, Makula teaches phospholipids of *Methylococcus capsulatus*, *Methylosinus trichosporium*.

Makula et al. teach phosphatidylethanolamine, phosphatidylglycerol, cardiolipin, and phosphatidyl-choline.

Additionally, Makula et al. teach esterified fatty acids as being predominantly C16:0 and C16: 1.

Kitagawa et al. and Makula do not teach the limitations of instant claim 21 and 24, wherein said animals are a human and an adult piscine species (fish), respectively.

However, Barrows does teach a method for producing feed particles of a desired size in a 20 to 1000.  $\mu\text{m}$  size range for uses in the production of human food articles (column 2, line 1). In accordance, Rawlings et al. teach a high lipid feed supplement, which can be formulated into fish food (column 8, line 1). No distinction has been made specifically in reference to larval or juvenile fish in the teachings of Rawlings et al.

Also, Rawlings et al. teach a process for making lipid-containing foodstuffs comprising solubilizing particulate proteinaceous matter, admixing a lipid material so as to form an emulsion, and contacting the emulsion with an effective amount of a pH adjusting agent to lower the pH to its isoelectric point, thereby aggregating the protein and simultaneously microencapsulating the lipid (Abstract only).

Rawlings et al. teach a process directed to the manufacture of low saturated fat and low cholesterol feedstuffs (column 2, lines 45-47).

Further, Rawlings et al. teach lipids in microencapsulation (column 2, line 57).

Fang et al teach the intact phospholipid profiles (IPPs) of seven species of methanotrophs from all three physiological groups, type I, II and X, were determined using liquid chromatography/electrospray ionization/mass spectrometry. In these methanotrophs, two major classes of phospholipids were found, phosphatidylglycerol (PG) and phosphatidylethanolamine (PE) as well as its derivatives phosphatidylmethylethanolamine (PME) and

Art Unit: 1614

phosphatidylmethylethanolamine (PDME). Specifically, the type I methanotrophs, *Methylomonas methanica*, *Methylomonas rubra* and *Methylobacterium album* BG8 were characterized by PE and PG phospholipids with predominantly C16:1 fatty acids. The type II methanotrophs, *Methylosinus trichosporium* OB3b and CSC1 were characterized by phospholipids of PG, PME and PDME with predominantly C18:1 fatty acids. *Methylococcus capsulatus* Bath, a representative of type X methanotrophs, contained mostly PE (89% of the total phospholipids). Finally, the IPPs of a recently isolated acidophilic methanotroph, *Methylocella palustris*, showed it had a preponderance of PME phospholipids with 18:1 fatty acids (94% of total). Principal component analysis showed these methanotrophs could be clearly distinguished based on phospholipid profiles. Results from this study suggest that IPP can be very useful in bacterial chemotaxonomy (Abstract only).

As disclosed above, Fang et al. teach methanotrophs of which the two most prominent classes consist of phospholipids.

Accordingly, Fang et al. disclose a representative of type X methanotrophs, contained mostly PE (89% of the total phospholipids). Finally, the IPPs of a recently isolated acidophilic methanotroph, *Methylocella palustris*, showed it had a preponderance of PME phospholipids with 18:1 fatty acids (94% of total).

It would have, thus, been *prima facie* obvious to one of ordinary skill in the art at the time of invention to at once recognize the reasonable expectation of success via the combining and/or the incorporating together the methods and inventions of Kitagawa et al and Makula A. with the teachings of Rawlings et al. and Fang et al.

Art Unit: 1614

Kitagawa et al. teach the central issue of invention via the disclosure of administration to a juvenile fish. According to the instant specification, this limitation is essential to the claimed invention. Fish in their larval or initial or first-feeding stages are more apt to yield higher predetermined concentrations of eicosapentaenoic acid and docosahexaenoic acid based on the above dietary administration. As a result of such administration, the larval fish develop lower blood levels of cholesterol. In conjunction with Kitagawa et al., Makula teaches the actual preferred bacteria/microbial lipid combination as disclosed. Makula teaches the actual configuration of the esterified fatty acid as C16:0 and C16: 1. Makula teaches *Methylococcus capsulatus* and its phospholipid composition consisting of phosphatidylethanolamine. The instant claimed invention discloses this combination as a feedstuff for fish, which aids in inducing lower cholesterol levels. Makula, thus, provides the initial motivation to combine with the teachings of Kitagawa et al., and further with Barrows and Rawlings et al. Barrows teaches the limitation of a feedstuff drawn to human food articles, thereby being for human consumption. Rawlings provides motivation to combine references based on the disclosure of a novel process disclosed [wherein] the *manufacture of low saturated fat, low cholesterol foodstuffs* [are] more palatable than those previously known (column 2, line 45-47). Rawlings provides further motivation to combine said references *supra*, due to teachings of feedstuffs being drawn to consumption via adult piscine species (fish) as opposed to larval/juvenile fish. Additionally, Rawlings et al. teaches microencapsulation of lipids to facilitate a more therapeutic administration. In accordance with the motivation to combine in view of primary references Kitagawa et al. and Makula, the secondary reference, Fang et al. teach the representative class of



microbes in claimed invention in association with a specific percentage of phospholipid content in formulation, which encompasses the specified percentages of the claimed invention.

In reference to a method for reducing plasma cholesterol of an animal or maintaining a reduced cholesterol level in an animal or reducing LDL: HDL cholesterol ratio in plasma of an animal, Kitagawa et al. teach a method of administration of a feedstuff, which is rich in the cholesterol lowering components eicosapentaenoic acid and docosahexaenoic acid to larval fish. Makula teaches the actual classification of a microbial lipid formulation, which is taught in Example 1 (pg 10) of instant specification. Fang et al teach the formulation process of methanotrophs or microbial lipids which is related to the teachings of Makula, i.e., *Methylococcus capsulatus* and its phospholipid composition consisting of phosphatidylethanolamine (methanotrophs). The teachings of Rawlings et al provide the distinct motivation to combine based on the disclosure of cholesterol lowering capabilities of foodstuffs for humans and fish.

Thus, the combination of references above arrives at achieving the instantly claimed objective of reducing plasma cholesterol in larval fish.

Instant claims 18, 21, 24, 27, 30,33, and 36-38 are made obvious over the teachings of the references *supra*.

### ***Conclusion***

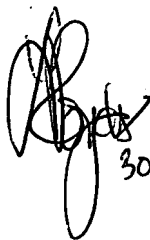
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

Art Unit: 1614

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB



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 10/1/07  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER